REMARKS

New claim 60 has been added and is supported in the specification at, for example, Figure 1.

The rejection of claim 53 to 59 as being indefinite has been overcome.

The rejection that independent claim 53 is indefinite with respect to the requirement for "attempting to withdraw" has been overcome by amendment by deleting the requirement.

The rejection of claims 53 to 59 for obviousness based on Truitt et al (U.S. Patent No. 5,910,252) in view of Glantz (U.S. Patent No. 5,749,835) is traversed.

The combination of Truitt et al and Glantz does not disclose several of the limitations (which are marked in bold below) of independent claim 53 including:

> a. **inserting a withdrawal needle in a surface peripheral vein in an extremity of the patient** ...
>
> * * * * * * *
>
> c. **determining that an insufficient amount of blood is entering the blood circuit from the withdrawal blood tube by determining that the blood entering the blood circuit is below a predetermined threshold amount of blood;**
>
> d. **in response to the determination, replacing the needle with a blood withdrawal catheter inserted in the surface peripheral vein, and maneuvering the catheter through the vein to position a tip of the catheter in one of a large vein, great vein or vena cava** to access a reservoir of blood for continuous blood withdrawal;

e. drawing blood from the reservoir of blood into the withdrawal catheter and into the withdrawal blood tube of the extracorporeal blood circuit,

Truitt and Glantz do not disclose the use of a withdrawal needle or a withdrawal catheter inserted in a surface peripheral vein for blood withdrawal, determining that an insufficient amount of blood is being withdrawn through the needle, and responding to the determination by replacing the needle with a blood withdrawal catheter that enters the peripheral vein and accesses a larger pool of blood in the venous system.

The invention is directed to a method to withdraw blood from a peripheral catheter having an extended length to reach a large or great vein or the vena cava the and withdrawal of blood by applying suction to the catheter and to a method in which an attempt to withdraw blood is first made by a withdrawal needle in a peripheral vein and thereafter blood is withdrawn by inserting an extended catheter into a peripheral vein to access a reservoir of blood in the large or great vein or vena cava. The claimed invention addresses a problem that arises in ultrafiltration when blood withdrawal through a peripheral vein is insufficient to provide the blood flow, e.g., less than 40 ml/min, for the intended treatment. The invention solves this problem by substituting a mid-length catheter for a short catheter needle. The mid-length catheter is introduced into a peripheral vein and extends through the veneous system to a large vein or other reservoir of blood in the patient.

The claimed invention would not have been obvious in view of the blood treatment device shown in Truitt and the method to locate a catheter shown in Glantz.

These references do not recognize the problem addressed by the inventor or suggest a solution to that problem. Glantz and Truitt provide no suggestion to form the claimed invention and would not render the invention to have been obvious.

Truitt does not suggest or teach peripheral vein access. Truitt discloses a blood treatment system that appears to access a central vein. *See* Truitt Fig. 1 (lines 33, 34 attach to torso of patient). Central vein access has traditionally be used to provide the large volume of blood used for ultrafiltration, hemofiltration and hemodialysis blood treatments. *See e.g.*, 6,685,664 (Background of the Invention). Central venous access lines tend to be much too large for peripheral vein access. It would be counter to such traditional blood treatment systems to rely on a narrow peripheral blood catheter to withdraw blood. It would have been counter-intuitive to use a narrow peripheral catheter tube to access a central vein. Truitt does not teach a method in which blood is first withdrawn from a surface peripheral vein, or a method in which a determination is made that the amount of blood through the surface needle is inadequate and thereafter a catheter is inserted into a peripheral vein of the patient to "one of a large vein, great vein or vena cava to access a reservoir of blood for continuous blood withdrawal."

Glantz does not teach inserting of a PICC catheter to withdraw blood. The peripheral vein PICC catheter disclosed in Glantz is for the delivery of medicaments. Glantz, col. 5, lns. 41-43, see also, col. 1, lns. 16-25. Other than disclosing a PICC catheter, Glantz is not material to the claimed invention. The teaching in Glantz of trimming the length of the PICC catheter does not amount to a suggestion that a PICC

catheter can be used to withdraw blood from a large vein, great vein or vena cava after being inserted through a peripheral vein.

There is no suggestion in Glantz to use a PICC catheter to withdraw blood into the Truitt blood treatment system. Glantz does not suggest that a narrow peripheral catheter is suitable for blood withdrawal in an ultrafiltration system, that a PICC catheter may be used to access large vein to avoid vein collapse or that a PICC catheter should be inserted after determining that a surface peripheral needle provides inadequate blood flow. There is no suggestion or motivation evident from the prior art to use a PICC catheter to withdraw blood from a central vein as a substitute for a peripheral catheter that accesses just a peripheral vein.

Secondary Consideration: Invention Recognized by Other As An Advancement In the Art

Jaski et al is a recognition of the invention in a peer reviewed article. As such, Jaski et al is a secondary consideration of non-obviousness. Jaski et al describes the same ultrafiltration system that is the subject of this application, and is evidence of non-obviousness. The ultrafiltration system described in this application, i.e., made by CHF Solutions, is the subject of the Jaski et al article.[1] [Jaski Article, p. 228.]

Jaski et al is secondary evidence of non-obvious because it shows that "conventional systems" where cumbersome and favorably discusses ultrafiltration using peripheral vein access. Jaski et al is an article published by the Journal of Cardiac Failure

[1] Jaski et al was prepared with the technical and financial support of the owner of this application.

and is a peer-reviewed article. The statements in the article regarding the benefits of peripheral access for ultrafiltration and the difficulties with the prior art central access support a finding that the claimed invention was not obvious. The recognition from peers in the art given to the invention in the Jaski et al is a secondary consideration of non-obviousness. *United States v. Adams et al.*, 148 USPQ 479, 484 (U.S. 1966)("Several of the same experts subsequently recognized the significance of the Adams invention.").

Contrary to the Action, Jaski et al does state that the invention is more desirable that prior art techniques. In particular, Jaski et al describes the use of a mid-length catheter ("25 or 35 cm") with the ultrafiltration system and, thus, is directly relevant to the subject matter claimed in this application. Jaski Article, p. 228. Jaski et al state that: "[t]o our knowledge, this is the first clinical report of rapid removal of extracellular and intravascular fluid volume excess via ultrafiltration without use of a central venous catheter," ("Discussion" heading at page 229); "[r]apid removal of extracellular and intravascular fluid volume excess can be safely achieved via peripherally inserted ultrafiltration without the need for central venous catheter placement" ("Conclusions" heading of the Abstract at page 227); and "[u]se of conventional systems, however, may be cumbersome, requiring physician placement of double-lumen central venous catheter ..." ("Background" heading of the Abstract at page 227). Accordingly, Jaski et al teach that central venous catheters are conventional for ultrafiltration, that peripheral vein access with a mid-length catheter successfully treated patients suffering from circulatory

volume overload, and that the use of a mid-length catheter inserted through a peripheral vein was less cumbersome than the prior art technique of central venous catheter access.

All claims are in good condition for allowance. If any small matter remains outstanding, the Examiner is requested to telephone applicants' attorney. Prompt reconsideration and allowance of this application is requested.

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /Jeffry Nelson/
Jeffry H. Nelson
Reg. No. 30,481

JHN:glf
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100